

REMARKS/ARGUMENTS

I. Status of Claims

- Claims 1 and 7 are Independent Claims.
- Claims 2-6 and 8 are currently amended.
- Claims 1-8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Seare et al. (US Pat. No. 5,557,514) (hereinafter referred to as **Seare**) in view of Ziegele et al. (PG Pat. No. US 2005/0125257) (hereinafter referred to as **Ziegele**) and further in view of Lockwood (US Pat. No. 5,706,441) (hereinafter referred to as **Lockwood**).

II. Response

A. Claims have been amended.

Claims 2-6 and 8 have been amended for grammatical formalities and to include a comma after the referencing antecedent claim number.

B. The combination of Seare with Ziegele and Lockwood teaches away from Independent Claims 1 and 7.

1. The definitions of “episode of care” and equivalent terms used in the prior art differ from the definition of “episode of care” used in the present invention.

Generally, words in a claim are to be given their plain meaning unless the plain meaning is inconsistent with the specification. See MPEP § 2111.01(I). Plain meaning refers to the ordinary and customary meaning given to a term by those of ordinary skill in the art. See MPEP § 2111.01(III). However, where an applicant chooses to deviate from the plain meaning, the applicant may become his own lexicographer and create a definition in the specification that differs from the plain meaning. See MPEP § 2111.01(IV).

Each of the cited prior art refers to “episode of care” and equivalents to include healthcare services. Specifically, **Seare** defines “episode of care” as “all healthcare services provided to a patient for the diagnosis, treatment, and aftercare of a specific medical condition.” See Seare, col. 23, ll. 9-12. **Lockwood** uses the term “sickness episode” and defines it as “a time period that begins when a patient is injured or begins to feel sick and ends when the patient is no longer sick or injured.” See Lockwood, col. 10, ll. 13-15. Furthermore, “each sickness episode data record built by system **80** will contain data representative of all diagnoses pertaining to the sickness episode, and all procedures and services performed by each health-care provider in the network in connection with the sickness episode.” See id. at ll. 23-29.

While **Ziegele** does not use either “episode of care” or an equivalent, **Ziegele** describes his invention through a “diagnostic information record,” whether historical or current. Yet, **Ziegele** apparently also focuses on healthcare services. For instance, **Ziegele** combines historical diagnostic information record and historical prescription information record that represents, for example, diagnostic information determined by a pre-determined set of sample medical professionals within a pre-determined period of time. See Ziegele, para. [0025]. Moreover, current diagnostic information record contain diagnostic information determined by doctors during patient visits. Id. at para. [0026].

In essence, when **Seare**, **Ziegele**, and **Lockwood** are combined, the combination teaches a invention that uses and/or focuses on healthcare services (e.g., all diagnoses, procedures and services by healthcare professionals) for episodes of care and diagnostic information records.

Here, Applicants’ “episode of care” does not include healthcare services. Defined as a group of diagnoses on the same patient that describes the course of a given illness, “episode of care” “does not depend on the nature of services delivered, the doctor delivering services, or the

site of services.” See Specification, para. [0025]. In addition, Applicants’ “episode of care” does not assume that services are temporally contiguous. Id. In essence, Applicants’ “episode of care” allows for overlapping episodes. Id.

It is important to recognize that such difference in definitions play a major impact on the teachings of the cited prior art and the present invention. While each of the prior art teaches the use of healthcare services for episodes of care, Applicants’ present invention teaches away from the use of healthcare services for episodes of care. In determining the severity of an episode of care, Applicants’ present invention focuses on the nature of the diagnosis, as opposed to the intensity of visits, as the basis for classifying visits into episodes. See Specification, para. [0005]. If healthcare services were to be included in Applicants’ present invention, then such inclusion would substantially change how Applicants measure the severity of an episode of care.

Hence, because of such significant difference in the definition, Applicants believe the combination of **Seare**, **Ziegele** and **Lockwood** does not teach the present invention. Therefore, Applicants respectfully request these obviousness rejections be withdrawn.

2. Ziegele’s correspondence probability calculates both diagnosis and prescription data, whereas Applicants’ probability calculation is based only on diagnosis data.

Examiner stated that while **Seare** does not teach a probability analyzer, **Ziegele** teaches a probability analyzer. See Office Action, 5 (03/19/07). Thus, Examiner believes that the combination of **Ziegele** and **Seare** (along with **Lockwood**), reads upon that of the present invention. Upon further review of **Ziegele**, Applicants respectfully disagree.

According to **Ziegele**, an automated data linkage technique can be generated by linking a plurality of diagnostic information records and a plurality of prescription information records.

See Ziegele, para. [0011]. This linkage creates a diagnosis-to-prescription relationship. Id. at para. [0014]. For each of these diagnosis-to-prescription relationships, a correspondence probability is determined between one or more of the diagnostic information records and one or more of the prescription information records. Id. at paras. [0014], [0023].

Therefore, a **Seare** and **Ziegele** combination teaches analyzing historical provider billings that uses **Ziegele's** automatic data linking technique. See Seare, Abstract ("A method and system for analyzing historical medical provider billings to statistically establish a normative utilization profile."); **Ziegele**, paras. [0011], [0014], [0023].

On the contrary, Applicants' probability analyzer is fundamentally different from that of **Ziegele**. First, it does not involve diagnostic and prescription data. Rather, it involves comparing only diagnostic data. See Specification, paras. [0027]-[0029]. In other words, the relationship that Applicants compares is a diagnostic-to-diagnostic relationship.

Second, the diagnostic data being compared are part of the same episode. See Specification, paras. [0027]-[0029]. Even though **Ziegele** calculates a correspondence probability based on diagnostic and prescription information records, **Ziegele** does not appear to be comparing such data against the same episode.

Because of these differences, Applicants believe **Ziegele's** probability analyzer does not read upon that of Applicants'. Therefore, Applicants respectfully request that this rejection be withdrawn.

3. Lockwood's severity analyzer differs from that of Applicants'.

Examiner noted that **Lockwood** uses a severity analyzer for performing episode severity calculations. See Office Action, 5 (03/19/07). Based on **Lockwood's** disclosure, Examiner

believes the combination of **Lockwood** and **Seare** (along with **Ziegele**) read upon Applicants' present invention. However, upon a closer review, Applicants respectfully disagree.

Lockwood does allow for an objective assessment of the severity of its sickness episodes. See Lockwood, col. 4, ll. 52-56. However, each of **Lockwood's** sickness episodes involves healthcare services. "Each sickness episode data record corresponds to an individual sickness episode for which health-care- services were performed for one of the patients by at least one health-care provider from the group of health-care providers." Id. at col. 4, ll. 48-52, col. 10, ll. 8-12, and Abstract. Furthermore, the severity scores of a case load complexity level are determined for each health-care providers within the group of health-care providers, where each case load complexity level represents a patient's case load that has been "serviced by a particular health-care provider within the group of health-care providers." Id. at col. 4, ll. 56-61 and Abstract.

As previously explained, **Seare** also focuses on healthcare services. See supra, § II.B.1-2. Since **Lockwood** also focuses on healthcare services, the combination of **Lockwood** with the other cited prior art thus necessarily revolves around healthcare services.

In contrast, Applicants' severity analyzer involves calculating the severity of episodes of care that do not involve healthcare services. See Specification, para. [0024]-[0025]. As discussed above, Applicants may be their own lexicographer. See supra, § II.B.1; see also MPEP § 2111.01(IV). Here, Applicants has specifically defined their "episode of care" to exclude healthcare services. See Specification, para. [0025] (stating that the "episode of care" definition "does not depend on the nature of services delivered, the doctor delivering services, or the site of services."). If Applicants were to include healthcare services in measuring the severity of episodes of care, Applicants would defeat their inventive purpose – to identify episodes of care

and measure their severity according to the nature of the diagnosis, as opposed to the intensity of visits. See Specification, paras. [0001], [0003]-[0006].

Because of this important distinction, **Lockwood** (in combination with **Seare** and **Ziegele**) therefore cannot read upon Applicants' present invention. Thus, Applicants kindly request withdrawal of the obviousness rejection.

4. Ziegele does not teach a probability calculation that operates on a pair of diagnosis records.

Applicants reiterate that **Ziegele** teaches a correspondence probability that compares diagnostic information records with prescription information records. See supra, § II.B.2. Such comparison creates a diagnostic-to-prescription relationship. Id. This relationship is not the diagnostic-to-diagnostic relationship taught in the present invention. Id.

Examiner identifies paragraphs [0079]-[0080] of **Ziegele** as a reference for operating specifically on a pair of records. See Office Action, 7 (03/19/07). However, Applicants believe **Ziegele** does not teach the claimed limitation.

Although **Ziegele** does use an example of two diagnoses (D_1 and D_2), these diagnoses are used to create combinations with three products (P_1-P_3). See **Ziegele**, para. [0079]. These combinations are further exemplified in **Ziegele's** table, showing combinations P_1D_1 , P_1D_2 , P_2D_1 , P_2D_2 , P_3D_1 and P_3D_2 . Id. Quite clearly, these combinations do not show pairs of diagnostic records.

Moreover, each of the diagnostic-to-prescription combinations is compared against a probability table to gather respective data record. See **Ziegele**, para. [0080]. If any these diagnostic-to-prescription combinations is not on the probability table, then they will not be considered. Id.

In contrast, Applicants' probability calculation does operate on a diagnostic-to-diagnostic record. See Specification, paras. [0027]-[0030], [0037]. For instance, a probability P_{ia} may be defined as "the probability that the diagnosis 'i' and diagnosis 'a' belong to the same episode." Id. at paras. [0027]-[0037]. This pair of diagnostic records may be a function of a similarity value and a time between diagnosis value. Id. at para. [0037] (noting that "the probability of being part of the same episode, P_{ia} , should be directly related to similarity of two diagnoses S_{ia} , and inversely related to T_{ia} , the time between the two diagnoses.").

Because of these differences, **Ziegele** (in combination with **Seare** and **Lockwood**) cannot teach the present invention. Thus, Applicants respectfully request Examiner to withdraw the obviousness rejections.

5. Ziegele does not teach a probability numerator and probability denominator as taught by Applicants' present invention.

Examiner noted that in **Ziegele**'s paragraph [0032], the probability is calculated by dividing a probability numerator by a probability denominator. See Office Action, 8 (03/19/07). While Applicants respect Examiner's judgment, Applicants once again reiterate that **Ziegele** teaches a correspondence probability that compares records based on a diagnostic-to-prescription relationship. See supra, § II.B.2. This relationship is not the diagnostic-to-diagnostic relationship taught in the present invention. Id.

In creating a probability table, **Ziegele** extracts historical good data files. From each historical good data file, all combinations of diagnostic information records and prescription information records, as well as the frequency of occurrence of such combinations, are determined. See Ziegele, para. [0032]. "The frequency of occurrence is determined from the historical good data file 222 by calculating how many times a particular diagnostic information

record is combined with a particular prescription information record [the probability numerator], and dividing that number with the total number of combinations in the historical good data file **222** [the probability denominator].” Id. In essence, the probability numerator relates to the frequency of a diagnostic-to-prescription relationship. The probability denominator relates to the total number of diagnostic-to-prescription combinations.

Here, Applicants’ probability calculation does not involve diagnostic-to-prescription relationships. As mentioned above, Applicants’ probability P_{ia} may be defined as “the probability that the diagnosis ‘i’ and diagnosis ‘a’ belong to the same episode.” See Specification, paras. [0027]-[0037]. By operating on a pair of diagnosis records, Applicants’ probability calculation involves only diagnostic-to-diagnostic relationships. See id. at para. [0037]. “The probability numerator may be set to the similarity value times a first constant, and the probability denominator may be set to the quantity of a second constant times the time between diagnosis value plus one.” Id. at para. [0038]. Similarity value relates to the similarity between a pair of diagnostic records (i.e., a diagnostic-to-diagnostic relationship), whereas time between diagnosis value relates to the time between a pair of diagnostic records (i.e., a diagnostic-to-diagnostic relationship). Id. at para. [0037].

By virtue of calculating different variables under different definitions for probability calculation, **Ziegele** cannot be combined with **Seare** (as well as with **Lockwood**) to read upon Applicants’ present invention. Thus, Applicants kindly request Examiner to withdraw the obviousness rejection.

6. Seare’s diagnosis pairs and the processing of diagnosis records in pairs differ from that of Applicants’ present invention.

Previously, in the office action response dated 12/08/06, Applicants explained their belief that **Seare** processes its data in bulk and does not disclose any diagnostic record that are paired or processed in pairs. See Amendment, 7-8 (12/08/06). Examiner responded in the 3/19/07 office action that he believes **Seare** does teach the processing of diagnostic records in pairs. See Office Action, 15 (03/19/07). However, while Applicants thank Examiner for identifying a reference point in **Seare**, a further review of **Seare** appears to reveal that this teaching is not the same as that of the present invention.

Examiner respectfully cited col. 24, ll. 38-40 as **Seare's** disclosure of the processing of diagnostic records in pairs. These lines state “[f]ourth, **1204**, once the data history has been searched for qualifying circumstances, the valid components of these patient records are then checked against the three inter-relational Index Tables to identify qualifying ICD codes associated with the chosen index code.” See **Seare**, col. 24, ll. 38-40. According to **Seare**, the three inter-relational Index Tables are the Index Table, Index Detail Table and Index Global Table. Id. at col. 7, ll. 17-25, col. 8, ll. 38-45, and col. 9, ll. 16-21 and 55-58.

These three inter-relational Index Tables have one thing in common: an episode of care. The Index Table “provides a preliminary filter for assigning and accessing different tables during the Episode of Care process.” See **Seare**, col. 8, ll. 51-53. The Index Detail Table, which groups ICD-9 codes into inclusive or exclusive diagnosis codes, provides a unique grouping for each index code and “is used to drive the search for each episode of care.” Id. at col. 7, ll. 35-37. The Index Global Table is used “to identify a generic V code or complication ICD code to be used in an EOC [episode of care] search for any Index code.” Id. at col. 9, ll. 44-46.

As discussed earlier, **Seare's** episode of care relates to “all healthcare services provided to a patient for the diagnosis, treatment, and aftercare of a specific medical condition.” See

supra, § II.B.1; see also **Seare**, col. 23, ll. 9-12. **Seare** further premises diagnosis data on such services by sorting raw data sets, which have undergone RAM [Read, Analyze and Merge] processing, “by index code (i.e. general diagnosis) to find all patient records with occurrence of a particular index code on at least two different dates of service.” See **Seare**, col. 24, ll. 18-21. By this definition and additional support, **Seare** intended to include healthcare services as part of a diagnosis.

However, each of Applicants’ diagnosis involves an episode of care that does not relate to healthcare services. In fact, Applicants purposely removed the notion of healthcare services from the definition of “episode of care” because Applicants’ present invention does not consider such services as part of its calculation of the severity of an episode of care. See Specification, para. [0025].

In addition, assuming **Seare** does disclose the processing of diagnostic records in pairs, as per Examiner’s cited reference, **Seare** merely uses these records for determining the episode of care. See Seare, Fig. 12, col. 23, l. 1 – col. 26, l. 22 (referring to section entitled “2. Determination of Episode of Care”). However, after making such determination, **Seare** seems to stop there. **Seare** does not further process these pairs by determining the probability of diagnoses belonging to the same episode. Furthermore, **Seare** does not analyze the severity of the episode based on the diagnosis pairs.

In contrast, Applicants go beyond selecting pairs of diagnoses for determining an episode of care. Here, Applicants select at least two diagnoses that are part of the same episode for calculating the severity of an episode. See Specification, para. [0027]. Whether two diagnoses are part of the same episode depends on the nature of the diagnoses and the time between each diagnosis. Id. Where a patient receives several diagnoses, the probability of two or more

diagnoses belonging to the same episode may be calculated. See Specification, para. [0031].

Once calculated, the pair-wise probabilities belonging to the same episode may be used to classify diagnoses into groups. Id.

As such, even if Examiner is correct in that **Seare** suggests that patient records are searched for co-occurring diagnoses, the diagnosis pairs in **Seare** are different from the diagnosis pairs in Applicants' present invention, based on the definition of "episode of care." Differences are also seen in the processing of diagnosis records in pairs. In sum, both **Seare** and Applicants' present invention involve different pairs of diagnosis records and process these pairs differently.

Hence, Applicants respectfully requests that the obviousness rejections be withdrawn.

C. Dependent Claims 2-6 and 8 depend on Independent Claims.

Because Dependent Claims 2-6 and 8 ultimately depend on their respective independent claims, the arguments presented for the independent claims also apply to these dependent claims. Therefore, Applicants respectfully request withdrawal of these objections.

Respectfully submitted,

/David Yee, Reg. No. 55,753/
David Yee
Registration No. 55,753

Office of Technology Transfer
George Mason University
4400 University Dr., MSN5G5
Fairfax, VA 22030
Phone: 703-993-3949
Fax: 703-993-8871

Filed: September 19, 2007